Monday,
December 6, 2010

Part IV

Department of Health and Human Services

Food and Drug Administration

Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Availability; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Notices
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion” dated December 2010. The guidance document notifies establishments that manufacture whole blood and blood components intended for transfusion about FDA approvals of biologics license applications for serological test systems for the detection of antibodies to Trypanosoma cruzi. These tests are intended for use as donor screening tests to reduce the risk of transmission of T. cruzi infection by detecting antibodies to T. cruzi in plasma and serum samples from individual human donors. The guidance document does not apply to the collection of source plasma. Also, the guidance does not apply to establishments that make eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The guidance announced in this document finalizes our recommendations for testing HCT/P donor screening and testing for T. cruzi antibodies contained in the draft guidance are not being finalized at this time because FDA believes additional discussion is warranted. Elsewhere in this issue of the Federal Register, FDA is publishing a 30-day notice announcing that the proposed collection of information for the guidance has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.


SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion” dated December 2010. The guidance document notifies establishments that manufacture whole blood and blood components intended for transfusion about FDA license approvals for serological test systems for the detection of antibodies to T. cruzi. These tests are intended for use as donor screening tests to reduce the risk of transmission of T. cruzi infection by detecting antibodies to T. cruzi in plasma and serum samples from individual human donors. The guidance document provides recommendations for one time testing of donations of whole blood and blood components for evidence of T. cruzi infection, blood donor and product management, labeling of whole blood and blood components, and procedures for reporting the implementation of a licensed T. cruzi test. The guidance document does not apply to the collection of source plasma. Also, the guidance does not apply to establishments that make eligibility determinations for donors of HCT/Ps.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Elsewhere in this issue of the Federal Register, FDA is publishing a 30-day notice entitled “Agency Information Collection
Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion,” which announces that the proposed collection of information has been submitted to OMB for review and clearance under the Paperwork Reduction Act. FDA will publish a notice concerning OMB approval of these information collection provisions in the Federal Register prior to the implementation date provided in the guidance document.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), 610.40, and 630.6 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: November 30, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.